REMARKS / ARGUMENTS

I. Status of the Claims

Claims 1-17 are pending in this application, of which, claims 6-17 are withdrawn from consideration. Claims 1-5 currently stand rejected. Claims 1-2 and 4 have been amended herein. New claims 18-20 have been added to recite aspects of the invention. The new claims are supported by the specification as filed and do not introduce new matter.

II. Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. With regard to this objection, the Office Action states:

> With respect to claim 1, there is no support in the disclosure as originally filed for a fluid collection bag having a fluid collection device. The fluid collection device 3 as disclosed is clearly and repeatedly disclosed as being an entity that is physically separated from the bag by a tube. Thus the bag cannot have the device as claimed. Claims 2-5 are rejected because they depend from claim 1.

Office Action at page 3. Applicants respectfully disagree with these rejections. In the interest of compact prosecution, Applicants have amended claims 1, 2, and 4 herein, and thus the rejections regarding these claims are moot. Applicants believe the amendments have put the claims in allowable form; accordingly, Applicants respectfully request allowance of these claims.

III. Rejections of Claims under 35 U.S.C. § 102(b)

Claims 1-3 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by O'Riordan et al, EP 583,148 A2, ("O'Riordan"). With respect to these rejections, the Office Action states:

> With respect to claim 1: O'Riordan teaches a method of collecting a biological fluid comprising collecting a biological fluid by natural flow via a needle (Page 3, lines 45-47) and without a pump, since the suction wand of the alternate embodiment of blood collecting means taught by O'Riordan is not used. The method further comprises the step of introducing a biological fluid collection bag 16 having a fluid collection device, i.e. the needle. With regard to limitations directed to the collection bag having a fluid collection device, in light of the rejection of claim 1 under 35 U.S.C. 112, the phrases "has a collection device" or "collection

device of the collection bag" are given their broadest reasonable interpretation in light of the specification, i.e. "have" or "of" is interpreted as meaning "operatively connected to". The fluid collection device/needle is proximate to a biological fluid source, namely the arteriovenous system of a patient, and the needle is in fluid communication with the bag 16. (Fig. 4, Page 3, lines 24-27, 45-47, Page 4, lines 53-55) O'Riordan discloses the step of allowing the biological fluid to flow through the biological fluid collection device of the collection bag 16 to the bag without the use of a pump, inasmuch as the pumps disclosed by O'Riordan are the vacuum pump for the suction wand, which is not present in the embodiment having a needle in place of the wand, and the anticoagulant pump, which does not interact in any way with the fluid collection device. The instant method also comprises the steps of measuring a fluid flow rate of the biological fluid via flow detector 22 (Page 5, lines 19-21), and pumping anticoagulant solution to the collected biological fluid at a solution flow rate. (Page 3, lines 51-55, page 4, lines 15-21, 47, 48) The solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant solution. (Page 3, lines 54, 55; Page 4, lines 15-48, Page 5, lines 19-23) Specifically, O'Riordan discloses in lines 47-48 that "with the above-described system, anticoagulant can be automatically delivered as a function of either volume of blood salvaged or the salvage rate" (i.e the volume of blood collected or blood collection fluid flow rate).

With respect to claim 2: The method taught by O'Riordan further comprises the step of pumping the anticoagulant and/or preservation solution to the collection bag 16 (Page 4, lines 53-55). The solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate Qb to preserve a selected ratio in the collection bag 16 between the collected biological fluid and the anticoagulant and/or preservation solution. (Page 4, lines 15-33)

With respect to claim 3: The biological fluid taught by O'Riordan comprises blood. (Abstract)

With respect to claim 5: The method taught by O'Riordan comprises a step of pumping anticoagulant, wherein the act of pumping comprises pumping using a peristaltic pump 42 having a variable rotation speed, inasmuch as the minimum pump speed can be set and the operation of the pump is controlled to ensure maintenance of the desired flow rate of anticoagulant. (Page 3, lines 54, 55; Page 5, lines 4, 5) The method also comprises adjusting the variable rotation speed to obtain the appropriate solution flow rate. (Page 3, lines 54, 55; Page 5, lines 4,5)

Office Action at pages 4-6. Applicants respectfully disagree with these rejections.

To form a basis for a § 102(b) rejection, a prior art reference must disclose each and every element as set forth in the claim. See MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") § 2131 (2007). "The identical invention must be shown in as complete detail as it is contained in the claim." *Id.* "The elements must be arranged as required by the claim." *Id.* With regard to independent claim 1, O'Riordan fails to disclose every element of the claim.

Specifically, O'Riordan does not disclose, at least, *collecting a biological fluid by natural flow, without a pump*, as required by amended independent claim 1. Although O'Riordan discloses some embodiments which utilize a suction wand (O'Riordan p. 3, lines 21-22) and others which utilize a needle (*Id.* p. 3, lines 45-48), the disclosure is explicitly limited to embodiments with a pump: "As embodied herein, the transporting means includes... a pump means such as a peristaltic pump or a vacuum pump for conveying fluid through tubing segment 22" (*Id.* p. 3, lines 25-27). As an illustration, O'Riordan's Figure 4 replaces the vacuum pump with a peristaltic pump, but it still collects blood with a pump. *Id.* p. 4, lines 56-58; Fig. 4. Hence, O'Riordan fails to disclose the limitation of *collecting a biological fluid by natural flow, without the use of a pump*. As such, O'Riordan does not disclose each and every limitation as set forth in independent claim 1.

Accordingly, Applicants submit that O'Riordan cannot be used to anticipate Applicants' claims as set forth in independent claim 1. The remaining claims rejected as anticipated by O'Riordan under 35 U.S.C. § 102(b) depend either directly or indirectly from independent claim 1. Accordingly, Applicants respectfully request withdrawal of this rejection with respect to claims 1-5.

IV. Rejections of Claims Under 35 U.S.C. § 103

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan. With respect to these rejections, the Office Action states:

> With respect to claim 4: The method taught by O'Riordan comprises a step of measuring a fluid flow rate Qb, wherein measuring a fluid flow rate of the biological fluid comprises calculating the variation in volume of the fluid collected, wherein such volume has an associated weight directly correlated to said volume by the density of the biological fluid. O'Riordan does not

> teach that measuring a fluid flow rate of the biological fluid comprises calculating the variation in weight of the fluid collected. However, the data accumulated by performing the step of measuring the variation in volume can easily be used by one of ordinary skill in the art to calculate variation in weight by multiplying the variations in volume by the density of the fluid (know because the fluid is blood) and multiplying the resulting mass variation by the gravitational constant to produce the associated weight variations. Therefore, it would be obvious to one of ordinary skill in the art to modify the method taught by O'Riordan such that the step of measuring fluid flow rate Qb further comprises the step of calculating the variation in weight of fluid collected with a reasonable expectation of success to monitor the amount of fluid collected to determine when a sufficient amount of blood has been collected and the process can be stopped.

Office Action at pages 6-7. Applicants respectfully disagree with these rejections.

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP § 2142. The examiner must show that the claimed invention "as a whole" would have been obvious to a person of ordinary skill in the art when the invention was unknown and just before it was made. *Id.* The showing must be made on the basis of the facts gleaned from the prior art without resorting to hindsight based upon applicant's disclosure. *Id.* All of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)." MPEP § 2143.01.IV.

The Office Action fails to state a *prima facie* case of obviousness. As previously discussed, O'Riordan fails to disclose, at least, *collecting a biological fluid by natural flow, without a pump*, as required by amended independent claim 1. Amended dependent claim 4 includes this limitation, as well as *calculating a variation in weight of the collected biological fluid, the pumped anticoagulant and/or preservation solution, and any anticoagulant and/or preservation solution remaining in the reservoir*. O'Riordan also fails to disclose calculating a variation in weight. In fact O'Riordan's Figure 4 teaches-away from the combination of these two limitations: weighing blood reservoir 16 with scale 40 is done only in conjunction with

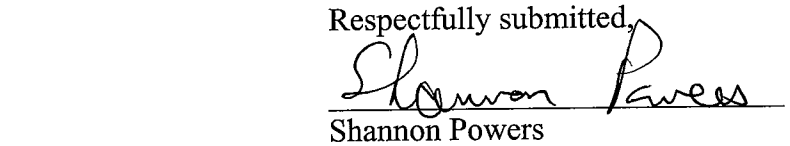
collecting blood with the use of peristaltic pump 42. O'Riordan p. 4, lines 52-58; FIG. 4. Since O'Riordan fails to teach or disclose either *collecting a biological fluid by natural flow, without a pump* or *calculating a variation in weight of the collected biological fluid, the pumped anticoagulant and/or preservation solution, and any anticoagulant and/or preservation solution remaining in the reservoir*, the Office Action fails to state a *prima facie* case of obviousness. For at least these reasons, Applicants respectfully request the withdrawal of the rejection of claim 4.

V. Conclusion

In light of the above amendments and remarks, which are supported by the specification, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections. Applicants further submit that the application is now in condition for allowance, and solicit timely notice of the same. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact the attorney of record.

The Commissioner is hereby authorized to debit Baker Botts L.L.P.'s Deposit Account No. 02-0383, Order Number 062908.0115, in the amount of $810.00 for the fee under 37 C.F.R. § 1.114 for the request for continued examination. Applicants believe that no additional fees are due. However, should the Commissioner deem that any fees are due, Applicants respectfully request that the Commissioner accept this as a Petition therefor and direct that any additional fees be charged to Baker Botts L.L.P. Deposit Account No. 02-0383, Order Number 062908.0115, for payment of associated fees, underpayment of fees, or to credit same with any overpayment of fees that may occur in association with this filing.

Respectfully submitted,



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